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Original Research Article

A randomized parallel group trial for the comparison of safety and efficacy of oral nifedipine retard versus intravenous labetalol in management of hypertensive emergencies of pregnancy

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Abstract

Background: Hypertensive emergencies during pregnancy pose significant risks to both mother and fetus. This study examines the time and dosage needed to achieve target blood pressure levels using two antihypertensive agents: oral Nifedipine retard and intravenous Labetalol. Through a randomized trial, it aims to provide insights into the safety and efficacy of these treatments, enhancing management strategies for hypertensive disorders in pregnancy.

Materials and Methods: A randomized study with 104 pregnant women who had a blood pressure of 160/110 mm Hg or higher compared the effects of Nifedipine (20 mg every 30 minutes, up to five doses) and Labetalol (20 mg, 40 mg, or 80 mg every 15 minutes) until a target blood pressure of 150/100 mm Hg or lower was reached. The main focus was on the time and dosage needed to achieve this goal.

Results: The mean time to achieve target blood pressure was significantly shorter with IV Labetalol (33.85 ± 11.87 minutes) compared to oral Nifedipine (48.56 ± 17.36 minutes; $P < 0.0001$). The average dose required was lower for Nifedipine (1.73 ± 0.63 mg) than for Labetalol (2.06 ± 0.67 mg; $P < 0.01$). The total dose needed was higher for Labetalol (70.00 ± 42.57 mg) compared to Nifedipine (33.71 ± 13.14 mg).

Conclusion: Labetalol quickly lowers blood pressure, while oral nifedipine retard is also effective and well tolerated for managing severe hypertension, showing minimal side effects.

Keywords: Hypertensive crisis, Pregnancy, Nifedipine, Labetalol.

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1. Introduction

About one in ten pregnant women are affected by a common medical disorder called hypertension. Examples of hypertensive diseases during pregnancy include gestational hypertension, pre-eclampsia, eclampsia, and pre-existing hypertension, with or without superimposed pre-eclampsia.[1,2]

One of the biggest causes of mother and neonatal deaths globally is still HDP. There are increased worsened perinatal outcomes disclosed because of severe hypertension.[1,3]

Severe pregnancy-induced hypertension occurs when the systolic blood pressure (SBP) is 160 mmHg or higher and the diastolic blood pressure (DBP) is 110 mmHg or higher.[4,5]

Between the 1990s and the early 2000s, global cases of hypertension disorders in pregnancy increased from 16.3 million to 18.08 million. Despite this rise, the age-standardized incidence rate declined by an estimated annual percentage of -0.68%. In 2019, there were approximately 27,830 deaths attributed to hypertensive disorders during pregnancy, marking a 30.05% decrease from 1990.[5]

We can diagnose preeclampsia even without proteinuria if the patients are found to have multiorgan damage.[6] Because of the potential of a stroke, intracerebral bleeding, hypertensive encephalopathy, and other end-organ damage, severe PIH needs to be treated right away. Furthermore, there is a higher chance of complications for the developing fetus, such as low birth weight, premature birth, hospitalisation of

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neonates in the ICU and surprisingly inappropriate death.[6,7] Also, it can lead to the risk of developing hypertension and dyslipidemia in early adulthood.[8] Starting the treatment for hypertension reduces the chance of hypertensive crisis and the risk of death of neonates.[9,10]

Labetalol works by blocking beta-1 receptors in the heart and alpha-1 receptors in blood vessels. This action leads to a dose-related decrease in blood pressure while maintaining a relatively stable heart rate. When administered intravenously, Labetalol takes effect within 5 minutes, with peak effects observed between 10 to 15 minutes. The duration of action is observed to range from 45 minutes to a maximum of 6 hours, offering a scope of effectiveness.[9]

Nifedipine, a calcium channel blocker of the dihydropyridine subclass, is money-saving for labourers. It is a hasty and prolonged action and can be ingested orally. However, it is expected to generate an unexpected reduction of blood pressure in the mother and severe pain in the fetus induced by placental hypoperfusion and palpitations that may occur if magnesium sulphate is administered simultaneously.[10]

Hydralazine dilates the blood vessels effectively and is the standard therapy for the management of severe PIH-complicating pregnancy. Currently, it is an alternative drug to Nifedipine and Labetalol for treating severe pregnancy-induced hypertension (PIH) due to its inconsistent effectiveness and adverse effects on the fetus.[10]

This research aims to compare the safety and efficacy of intravenous Labetalol versus oral Nifedipine retard in managing hypertensive emergencies during pregnancy.

2. Materials and Methods

The research was conducted at Shri B.M. Patil Medical College, Hospital, and Research Centre from September 2022 to April 2024, included pregnant women between the ages of 18 and 40 admitted to the Labor Room with period of gestation more than 28 weeks with Blood pressure ≥160mmHg and DBP ≥100 mmHg and agreeing to give written and informed consent participated in this randomised control study. A detailed history and general physical examination were taken.

Participants were pregnant women with hypertensive emergencies (Severe pre-eclampsia / Imminent eclampsia), maternal age above 18 years, and gestational age > 28 weeks. Women were excluded from the study if they had a history of medical disorders such as diabetes, heart disease, kidney disease, thyrotoxicosis, hemophilia, or chronic hypertension. Additionally, women in active labour, those who received any other antihypertensive medication prior to admission, patients presenting with intrauterine death, and those with eclampsia were also excluded.

A total of 104 pregnant women with Hypertensive emergencies attending the outpatient department were included and divided into 2 groups of 52 each; Group A was given IV labetalol, while Group B was given oral Nifedipine retard 20 mg.

2.1. Study parameters

In Group A, participants initially received an intravenous dose of Labetalol at 20 mg, 40 mg and 80 mg in increasing order. They could receive up to 5 doses every 15 minutes until the target blood pressure has been achieved. Blood pressure monitoring was done in all subjects every 15 minutes, and if the target was not reached, additional doses of 40 mg or 80 mg were administered until the goal was met.

In Group B, the participants were initially given an oral dose of 20 mg of Nifedipine retard (extended-release). The blood pressure of the study participant was checked every 15 minutes, and a tablet of oral nifedipine retard 20mg was given every 30 minutes till the goal blood pressure has reached systolic blood pressure (SBP) of less than 150 mm Hg and diastolic blood pressure (DBP) between 80 and 100 mm Hg.

Vital signs were monitored closely, and maternal blood pressure was measured at 15-minute intervals throughout the study, with any adverse effects of the medications recorded.

This study was approved by the Institutional Ethical Committee at BLDE University (approval number BLDE (DU)/IEC/763/2022-23) and is registered with the Central Trial Registry of India (registration number CTRI/2023/06/053461).

Statistical processing: Data were recorded in Microsoft Excel and analyzed with SPSS (Version 20). Results are presented as means ± standard deviations (SD) and includes graphs and counts. Differences in normally distributed continuous variables were evaluated with an independent t-test, with p-values < 0.05 considered statistically significant.

3. Results

104 individuals participated in the study, primarily within the 18-24 age group. In the IV Labetalol group, 51.9% were in this age range, while the Oral Nifedipine group comprised 48.0%, making this demographic a substantial 50.3% of the overall sample. The next largest age group was 25-29 years old, which included 15 individuals in Group A and 17 in Group B, accounting for 30.7% of the total participants. The older demographic, those aged 30 and above, represented a smaller portion of the sample, with 9 individuals in Group A and 8 in Group B, totalling 16.3%. The smallest group was those over 35 years old, consisting of only 1 individual in Group A and 2 in Group B, which made up 2.9% of the total sample. This distribution pattern strongly indicates a predominantly young adult population, emphasising individuals in their early to mid-twenties. The mean age of women in Group A was 24.73 ± 4.678 years, and the mean

age in Group B was 25.08 ± 3.915 years, with a p-value of 0.16.

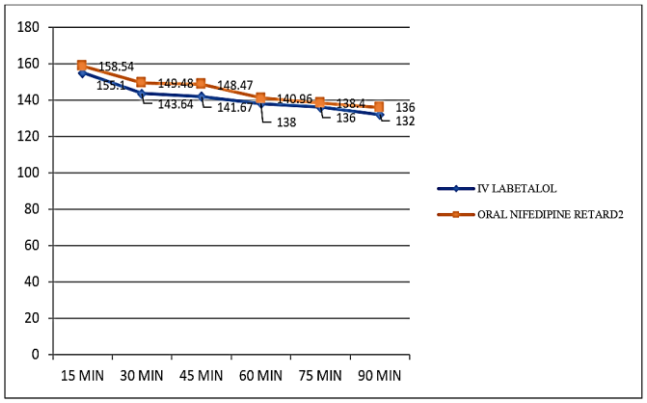

Figure 1: Mean of systolic blood pressure at 15min, 30min 45min, 60min, 75min, 90min (Group A -IV Labetalol, Group B- Oral nifedipine)

Out of the 104 women studied, 51 were primigravida (first-time pregnancies), and 53 were multigravida (having had previous pregnancies). The analysis yielded a p-value of 0.11, indicating no statistically significant difference between the two groups. Additionally, with a p-value of 0.55, it was found that most individuals with pre-eclampsia were in the term gestation stage.

The majority of patients with pre-eclampsia were between 38 and 40 weeks of gestational age. The mean gestational age for Group A was 38.02 ± 2.339 weeks, while for Group B, it was 37.69 ± 3.190 weeks.

When comparing the total time needed to achieve goal blood pressure using an independent t-test between IV Labetalol and oral Nifedipine, the findings were very significant (p-value 0.001): the time needed to reach goal blood pressure was 33.85±11.866 minutes labetalol and 48.56±17.358 minutes for Nifedipine retard (**Table 1**). The average number of doses administered for IV labetalol was 2.06 ± 0.669, and for oral nifedipine, retard was 1.73 ± 0.630, with statistically significant outcomes (p-value = 0.01). (**Table 2**)

In the Labetalol group, 7 patients (13.4%) experienced headaches, 2 patients (3.9%) experienced abdominal pain, and in the Nifedipine group, 12 patients (23%) experienced tachycardia. When comparing side effects in the two groups, the results were found to be significant (P=0.04).

Most of the patients underwent cesarean section, 40(76.9%) in IV Labetalol and 43(82.7%) in the Oral Nifedipine group. Results were found to be insignificant (p-value 0.361) when comparing delivery in IV Labetalol and Oral Nifedipine groups. Postpartum eclampsia was seen in 1(1.9%) patient in group B (oral nifedipine retard). Not a single woman died during the study period.

Most newborns were given mother side, i.e. 31(59.6%) in IV Labetalol and 37(71.2%) in Oral Nifedipine. When comparing fetal outcomes in IV Labetalol and Oral Nifedipine, the results were insignificant (p=0.37).

Table 1: Comparison of mean of time (minutes required to achieve target BP)

Drug	Mean	Std. Deviation	Mean diff	p-value
IV Labetalol	33.85	11.866	-14.712	<0.001**
ORAL Nifedipine	48.56	17.358		

**highly significant

Table 2: Comparison of mean number of doses required to achieve target BP

Drug	Mean	Std. Deviation	Mean diff	p-value
IV Labetalol	2.06	.669	.327	.01*
Oral Nifedipine	1.73	.630		

*Statistically significant

4. Discussion

The study findings revealed no statistically significant difference between the two groups concerning their general characteristics, including age, parity, gestational age, proteinuria, oedema, mode of delivery, fetal outcomes, and birth weight. These results align with those reported in the literature.

In the present study, age comparison was not significant among either group. All the patients were aged between 19-35 years in the present research. A survey by Sahai R et al. [13] has shown that the mean age (years) in the nifedipine and labetalol groups was 23.42 and 22.90 years respectively (p < 0.648). Similar results were noted in other studies.

4.1. Comparison of mean time required to attain goal BP

In the present study, the average time which was required to reach the target blood pressure was 33.85 minutes for the group receiving intravenous Labetalol and 48.56 minutes for the group receiving oral nifedipine retard, with a highly significant p-value of less than 0.001. This indicates that intravenous Labetalol was more effective in achieving the target blood pressure compared to oral nifedipine retard.

In a study conducted by SK Biswas et al.[11] in 2023, the mean time to reach the target blood pressure with Labetalol was 30.33 ± 10.44 minutes, while for oral Nifedipine, it was 25.63 ± 10.12 minutes. Jamil S et al[13] also found that the mean time to achieve the target blood pressure in the nifedipine and labetalol groups was 30.6 and 34 minutes (p=0.09).

4.2. The mean number of doses given in both groups to reach the target BP

In the present study, we found that the mean number of doses required for intravenous (IV) labetalol was lower (1.73) compared to oral Nifedipine retard (2.06) (p=0.01, statistically significant). Additionally, a randomised controlled trial conducted by Sharmai M et al.[1] indicated that women who received Nifedipine needed significantly fewer doses to control their blood pressure, with a mean dose of 1.8 ± 1.1 (SD) compared to 2.6 ± 1.2 (SD) in the labetalol group. Furthermore, another randomised controlled study by Alam A et al[10] demonstrated that the mean number of doses required in the Nifedipine and Labetalol group was 1.75 and 2.18 respectively (p=0.024, statistically significant).

4.3. Comparison of side effects

In the present study, most of the patients, 35(67.3%) of IV Labetalol and 30(57.5%) of Oral Nifedipine group B did not experience any side effects. In Group A, 7(13.4%) patients had Headaches and 2(3.9%) patients had abdominal pain, and in Group B, 12(23%) had tachycardia. Results were found to be significant (p-value 0.04) when comparing side effects in both groups. Sharma M et al also found that Nifedipine showed tachycardia as a side effect, and there were no side effects in the IV labetalol group.[1]

4.4. Comparison of mode of delivery

In this study, the vaginal delivery rates were recorded at 21.2% for the labetalol group and 16.5% for the nifedipine retard group. In contrast, the rates for cesarean section deliveries were significantly higher, with 76.9% for labetalol and 82.7% for nifedipine retard. The statistical analysis revealed no significant difference, as indicated by a p-value of 0.361. Gavit et al in 2018 conducted a comparative observational study that found 62.5% of participants in the labetalol group delivered vaginally, compared to 65% in the nifedipine group.[15] The cesarean section rates were 37.5% for the intravenous labetalol group and 35% for the oral nifedipine group (p=0.816). However, in this study, the rates of vaginal delivery were higher compared to those of cesarean sections.

4.5. Comparison of fetal outcome

In the present study, in the IV labetalol group, 23(44.2%) were admitted to the NICU, and in oral nifedipine retard group, 13(25%) were admitted to the NICU and results were found to be significant in terms of NICU admission. Out of this, 1(1.9%) of Group A and 3(5.8%) of Group B were dead after 2 days of admission. In a prospective comparative study conducted by Nivethana KB et al. in 2019, it was found that 1 (4%) newborn was admitted to NICU in the IV labetalol group, while 8 (32%) in the oral nifedipine group.[12]

In this study, the mean birth weights in the labetalol and nifedipine groups were 2.4769 and 2.5602, respectively. Nivethana KB et al. reported a mean weight of 2.23 in the nifedipine group and 2.89 in the labetalol group, which also showed no statistically significant difference between the groups.[12]

The strength of the study lies in its clear demonstration that, despite a population of only 104 women, the statistical analysis strongly supports the finding that intravenous Labetalol reduced blood pressure more rapidly than oral Nifedipine retard. However, a fundamental limitation of the study is that most of the patients with pre-eclampsia or imminent eclampsia had received another antihypertensive drug before admission, which may have influenced the outcomes.

5. Conclusion

This study was done so that a positive step can be taken toward finding out whether oral tablets are equally efficacious in reducing blood pressure compared with IV as they are simple, flat, and cheaper for poor people. The present study findings show that an intravenous labetalol regimen is the most effective method for rapidly reducing blood pressure during hypertensive emergencies, such as severe pre-eclampsia. Although IV labetalol effectively maintains lower blood pressure in a short time, oral nifedipine retard is also effective and very well-tolerated for rapid control of blood pressure in hypertensive emergencies, with minimal side effects reported in the present study.

6. Source of Funding

None.

7. Conflict of Interest

None.

8. Ethical Approval

Ethical no.: BLDE(DU)/IEC/763/2022-23.

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